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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
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ART UNIT	PAPER NUMBER
1812	98

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This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

- ☒ Responsive to communication(s) filed on 2/25/97
- ☒ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 53, 55 to 63, 66 to 68, 70 to 74, 76, 77, 79 to 98 is/are pending in the application.
- Of the above, claim(s) _____ is/are withdrawn from consideration.
- ☒ Claim(s) 79, 81, 85 is/are allowed.
- ☒ Claim(s) 53, 55 to 63, 66 to 68, 70 to 74, 76, 77, 80, 82 to 84, 86 to 98 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☐ Notice of Reference Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

—SEE OFFICE ACTION ON THE FOLLOWING PAGES—

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1) Claims 53, 55 to 63, 66 to 68, 70 to 74, 76, 77 and 79 to 98 are pending in the instant application. Claims 54, 75 and 78 have been canceled, 53, 55 to 63, 66 to 68, 71, 72, 76, 77, 82 to 84 and 91 to 93 have been amended and claims 97 and 98 have been added as requested by Applicant in Paper Number 31, filed 25 February of 1997.

2) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3) Any objection or rejection of record which is not expressly repeated in this Office Action has been overcome by Applicant's response and withdrawn.

4) Claims 53 to 63, 66 to 68, 70 to 77, 86, 88 to 92 and 95 to 98 are rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is enabling only for claims limited to a nucleic acid encoding one of the subunits which is encoded by the biological material that was deposited as described in lines 10 to 14 on page 19 of the instant specification for those reasons of record in section 7 of Paper Number 26. Claim 97, for example, encompass a nucleic acid encoding a beta2 subunit of a human nicotinic acetylcholine receptor. The term "nicotinic acetylcholine receptor" is a class of receptors. The term "beta2 subunit of a human nicotinic acetylcholine receptor" is defined in the text in lines 34 to 31 on page 11 of the instant specification in terms of the deposited biological material. The

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instant specification does not identify that property or combination of properties of a "beta2 subunit of a human nicotinic acetylcholine receptor" which distinguishes that protein from any structurally related protein. The only material limitation recited in this claim is that the protein encoded by the claimed nucleic acid "comprises a sequence of amino acids encoded by the sequence of nucleotides set forth in SEQ ID No. 9". No reading frame or minimum length of amino acid sequence is given. Essentially, this claim encompasses any nucleic acid encoding a beta subunit of a human nicotinic acetylcholine receptor whose amino acid sequence comprises at least two contiguous amino acid residues which could be encoded by SEQ ID NO:9 of the instant application. The instant application, however, only provides an adequate written description of the deposited biological material described therein. It does not disclose how to make and use any nucleic acid other than that which is contained in that material.

Applicant has urged that the disclosed nucleic acids can be employed to isolate related nucleic acids from DNAS libraries. Such an assertion raises two issues. The first is whether the disclosed nucleic acids and proteins would be predictive of nucleic acids obtained by such methods. *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970), held that

"Inventor should be allowed to dominate future patentable inventions of others where those inventions were

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based in some way on his teachings, since such improvements while unobvious from his teachings, are still within his contribution, since improvement was made possible by his work; however, he must not be permitted to achieve this dominance by claims which are insufficiently supported and, hence, not in compliance with first paragraph of 35 U.S.C. 112; that paragraph requires that scope of claims must bear a reasonable correlation to scope of enablement provided by specification to persons of ordinary skill in the art; in cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific law; in cases involving unpredictable factors, such as most chemical reactions and physiological activity, scope of enablement varies inversely with degree of unpredictability of factors involved."

In the instant case, to suggest that the disclosed nucleic acids are predictive of related nucleic acids would be to extrapolate from a single data point, which is scientifically unsound.

Further, in the absence of material limitations the instant claims constitute nothing more than a wish to know the identity of any nucleic acid which encodes a human protein which is related to those encoded by the deposited biological material. Amgen Inc. v. Chugai Pharmaceuticals Co. Ltd., 18 U.S.P.Q. 2d, 1016, held that;

"A gene is a chemical compound, albeit a complex one, and it is well established in our law that conception of a chemical compound requires that the inventor be able to define it so as to distinguish it from other materials, and describe how to obtain it. See *Oka*, 849 F.2d at 583, 7 USPQ2d at 1171. Conception does not occur unless one has a mental picture of the structure of the chemical, or is able to define it by its method of preparation, its physical or chemical properties, or whatever characteristics sufficiently distinguish it. It is not sufficient to define it solely by

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its principal biological property, e.g., encoding human erythropoietin, because an alleged conception having no more specificity than that is simply a wish to know the identity of any material with that biological property. We hold that when an inventor is unable to envision the detailed constitution of a gene so as to distinguish it from other materials, as well as a method for obtaining it, conception has not been achieved until reduction to practice has occurred, i.e., until after the gene has been isolated"

Applicant's arguments regarding generic inventions are inapplicable to the instant claims because the instant specification does not disclose a generic invention. It does not describe a plurality of inventions having a common element or combination of elements which have a common utility and reflects an inventive contribution. The instant specification discloses three different chemical compositions which do not reflect a common inventive element and provides only one example of each composition. If Applicant will kindly review page 1404 of In re Wands, they will find that the factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and, (8) the breadth of the claims. The instant specification provides only one example of each of the three different proteins encoded by the claimed nucleic

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acids. It provides no guidance with regard to whether additional related proteins will vary both structurally and functionally from those which are disclosed in the instant specification. To produce other embodiments of the claimed invention would require a practitioner to make an inventive contribution at least as great as that made by Applicant since nucleic acids other than those that are disclosed would have to be characterized both structurally and functionally. The only material which is encompassed by the instant claimed that can be made and used by a practitioner without the need for undue experimentation is that material which has already been made and used by Applicant.

5) Claims 53 to 63, 66 to 68, 70, 72 to 74, 79 to 84, 86 to 92 and 95 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5.1) Claims 53, 54 and 58 each recites an improper Markush group because the elements recited therein do not possess a common property which is mainly responsible for their function on the claimed relationship. Contrary to Applicant's assertions, any claim which recites alternate embodiments for a particular element is a Markush claim irrespective of what Applicant wishes to call it. See M.P.E.P. 2173.05(h). These are three distinct proteins which can not be used interchangeably in the claimed

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invention. Claims 55 to 57, 59 to 63, 66 to 68, 70, 79 to 84, 86 to 92 and 95 are incorrect in so far as they depend from any of claims 53, 54 or 58 for this element.

5.2) Claims 55 and 56, 72, are incorrect because there is no antecedent basis for "the" sequence of amino acids encoded by the referenced nucleotide sequences. There are no coding regions indicated in any of those nucleotide sequences which can be read in any one of three reading frames.

5.3) Claim 57 is incorrect in referring to "high stringency to a the nucleic acid". This is also incorrect because it is the claimed nucleic acid which hybridizes to the nucleic acid of claim 53, not the nucleotides.

5.4) Claims 59 to 61 are incorrect because there is no antecedent basis for "the nucleic acids" as explained in section 8.4 of Paper Number 26.

5.5) Claim 66 is incorrect because it drawn to "The of claim 59".

5.6) Claim 67 is incorrect because there is no antecedent basis for "The cell of claim 66".

5.7) Claims 73, 74, 86 are vague and indefinite because the term "substantial homology" has no clear meaning in the art and it is not possible to determine what is encompassed and what is excluded by this term for those reasons of record in section 8.7 of Paper Number 26. The term "substantial" simply means not

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imaginary. The term "homology" indicates that the referenced item has an analogous structure or function relative to an item from a different organism. Claims 76 and 77 are indefinite in so far as they depend from either of claims 73 or 74 for this element. Applicant's traversal of this rejection on the premise that such language appears in claims of issued U.S. Patents is irrelevant since all applications are decided on their own merits. Unless Applicant can clearly identify that material which is included and excluded by this limitation it is ambiguous.

5.8) Claim 92 is incorrect because of the word "comprisinga".

6) Claims 55, 56, 76, 77, 82 to 84 and 98 are rejected under 35 U.S.C. § 112, fourth paragraph, as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant has traversed this rejection on the premise that a dependant claim merely needs to incorporate all of the limitations of the claim from which it depends. If Applicant will review this statute in its entirety they will find that it is the claimed subject matter which must be further limited by a dependant claim. A protein is not a further limitation of a nucleic acid because these are two chemically and structurally unrelated compounds.

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7) Claims 55, 56, 76 to 78 and 82 to 84 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by the Whiting et al. publication (J. Neuroscience 8(9):3395-3404, Sep. 1988). The limitation "isolated" simply requires the recited compound to be found in any state of purity that is higher than occurs in nature. These claims, as written, are anticipated by nothing more than a membrane preparation from any cell line or tissue which contains one of the disclosed receptor subunits since that subunit has been isolated from the nuclear and cytoplasmic material with which it normally associates in nature. In the instant case Figure 5B on page 3400 of Whiting et al. described several sucrose gradient fractions which clearly meet all of the limitations of the pending claims.

8) Claims 79, 81, and 85 are allowable as written.

9) Applicant's arguments filed 25 February of 1997 have been fully considered but they are not deemed to be persuasive.

10) **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE

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STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm at telephone number (703) 308-4008. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:30 PM. The fax phone number for this group is (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



JOHN ULM
PRIMARY EXAMINER
GROUP 1800